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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HAYES, MICHAEL J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 10/01/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/690,473

Applicant(s)

HAARALA ET AL.

Examiner

Michael J Hayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 60-131 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 60-131 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/16/02 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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Claims 60, 61, 63-68, 70-72, 74-~~78~~<sup>79</sup> are rejected under 35 U.S.C. 102(b) as being anticipated by HANCOCK et al. (U. S. Patent No. 4,840,615). Hancock discloses an access port having upper and lower bodies, an outlet for attaching a catheter, entry and access sites located throughout a common septum, whereas the entry and access sites include perpendicular sites to each other or to the outlet that extend in a direction away from the reservoir to help define the reservoir volume and the wall thickness of the device. Hancock discloses that the septum outer surface is exposed exteriorly in one embodiment (5:16-20). See also Figs. 1, 4, 5, 9, 19 and related text.

Claims 60-112 are rejected under 35 U.S.C. 102(b) as being anticipated by DALTON (U. S. Patent No. 4,857,053). Dalton discloses an access port made from titanium having upper and lower bodies, an outlet for attaching a catheter, suture holes, entry and access sites located in a common septum that are perpendicular to each other or to the outlet, extending in a direction away from the reservoir to define reservoir volume and septum wall thickness. The upper body or body portion 30 includes target areas or holes for entry and access sites. See Figs. 4-6 and related text.

Claims 81-85, 88, 89, 91-96, 99, 100 are rejected under 35 U.S.C. 102(b) as being anticipated by CONE et al. (U. S. Patent No. 5,108,377). Cone discloses an access port including titanium body portion of upper and lower body parts, reservoir, outlet, entry site defined by a hole in the portion. The septum is located horizontally between the septum and lower body part as seen in Fig. 3. The access and entry sites are located in the common septum

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Claims 102, 103, 104, 105, 107, 108, and 110-112 are rejected under 35 U.S.C. 102(e) as being anticipated by TUCKER. Tucker discloses an access port including a titanium body portion of upper and lower parts, reservoir, outlet with catheter, septum having access and entry sites defined by a target hole, and suture holes. See Figs. 1,2.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 60-65, 68, 69, 81-85, 89-96, 100-107, 111, and 112 are rejected under 35 U.S.C. 103(a) as being unpatentable over MITTLEMAN (U. S. Patent No. 4,000,740) in view of TUCKER (U. S. Patent No. 5,718,682). Mittleman discloses an access port including upper and lower 12 body portions, a guidewire/stylet entry site 16 sealed with a septum 26, and an access site 42. Mittleman discloses the access site orientated perpendicular to guidewire site and the outlet because the site is placed perpendicular to an axis line drawn between the guidewire site and the outlet. Mittleman does not disclose making the device of titanium or suture holes. Tucker teaches the use of titanium and suture holes to provide a nonreactive metal for the delivery of medications and to hold the device in place on a patient. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Tucker in the device of Mittleman in order to provide a device compatible with bioactive fluids and to prevent injury during use that would result from the device moving in relation to the patient.

Claims 62, 69, 73, 80, and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over HANCOCK or CONE as applied to claims 60, 70, or 91 above, and further in view of TUCKER. Hancock discloses the claimed invention except for using titanium to make the device and suture holes. Cone discloses the claimed invention except for suture holes. Tucker discloses the use of titanium and suture holes to provide a nonreactive metal for the delivery of medications and to hold the device in place on a patient. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Tucker in the invention of Hancock or Cone to provide a device compatible with bioactive fluids and to prevent injury during use that would result from the device moving in relation to the patient.

Claims 113-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over HANCOCK, DALTON, CONE, MITTLEMAN and/or TUCKER and further in view of LUTHER (U. S. Patent No. 5,403,283). Hancock, Dalton, Cone, Mittleman and/or Tucker disclose the recited invention as discussed above with respect to claims 60, 70, 81, 91, and 102 except for a stylet. Luther teaches the use of a stylet 22 for introducing a catheter into the septum of a port (2:44-60). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Luther in the inventions of Mittleman and Tucker, Hancock, Cone, or Tucker alone in order to provide a safe method of catheterizing a port.

Claims 113-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over HANCOCK, DALTON, CONE, MITTLEMAN and/or TUCKER and further in view of ENSMINGER et al. (U. S. Patent No. 5,556,381). Hancock, Dalton, Cone, Mittleman and/or Tucker disclose the recited invention as discussed above with respect to claims 60, 70, 81, 91, and 102 except for a stylet. Ensminger teaches the use of a stylet for accessing an implanted

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catheter of a port (8:39-50). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Luther in the inventions of Mittleman and Tucker, Hancock, Cone, or Tucker alone in order to provide a safe controllable method of percutaneous access.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9302. The fax number for submitting after final papers is (703) 872-9303.

mjh  
26 September 2002



**MICHAEL J. HAYES  
PRIMARY EXAMINER**